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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,555	10/15/2001	Barry J. Marshall	BAL-99A (16843)	1969

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EXAMINER

GUO, LYNDIA T

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 12/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,555

Applicant(s)

MARSHALL ET AL.

Examiner

Lynda T Guo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 15 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-6
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Status of the Application

The IDS PTO-1449 (Paper No. 4, 5 and 6 - file on 18 February 2002, 24 April 2002 and 13 November 2002, respectively) have been received and entered.

Claims 1-22 of the present Application are pending.

Information Disclosure Statement

1. The information disclosure statement (Paper No. 6) filed on 13 November 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 8 and 13 recite the limitation "said first composition". There is insufficient antecedent basis for this limitation in the claim because the independent claim, Claim 1, recites "a first **powdered** composition".

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Claims 2-13 should be rewritten as, "**The** method..." as opposed to "**A** method..." for proper dependency since Claims 2-13 are limiting only toward **the** method of Claim 1. (This also applies to Claims 15-17, which are dependent on Claim 14 **and** Claims 19-22, which are dependent on Claim 18.)

The phrase "urea being capable of being converted into ammonia" in Claim 1, 14 and 18 is indefinite. Urea always converts to ammonia when reacted with urease. Therefore, Examiner suggests the Claims be rewritten as, "urea **being** converted into ammonia..." or "urea **is then** converted into ammonia...".

In Claim 10, the word, "comprising" is in improper verb tense.

In Claims 11, 12 and 16, the term, "pH adjuster" is indefinite and not commonly used in the art.

4. Claims 1, 14 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps.

See MPEP § 2172.01. The omitted steps are: the determination steps (i.e. how is the presence/absence of ammonia determined). Standard method steps include contacting, determining and correlating.

Allowable Subject Matter

5. The closest prior art found are USPN 4,748,113 and USPN 5,314,804. Summaries of the three inventions are as follows:

USPN 4,748,113 discloses of compositions and methods for the diagnosis of gastrointestinal disorders involving urease. The composition disclosed comprises urea, a bactericide, an indicator, a gelling agent such as agar and a buffer. The method disclosed comprise obtaining a

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sample of gastric material from a subject, contacting said sample to the claimed composition and then observing for a change in color of the composition.

USPN 5,314,804 discloses of a method and a device for determining the presence of *Helicobacter pylori* in a biological tissue sample by detecting the presence of urease in the tissue. According to this device, a tissue sample is placed onto an element permeable to ammonia. The sample is then contacted with a urea solution so that ammonia forms and permeates through the element to come in contact with an indicator. Any change in color of the indicator is then observed.

Methods for detecting urease in a gastrointestinal system are well known in the art. Standard methods utilize urea as a substrate so that the resulting ammonia can be detected via color changes to a pH indicator. The two inventions summarized above are representative of tests that have been available for detecting urease in a gastrointestinal system. They are also the closest prior art that encompass many limitations of Applicant's claimed invention. For example, the method of contacting a gastric sample to urea composition and then to an indicator composition is similar to that disclosed in USPN 5,314,804. The various other components (e.g. agar, bactericide or bacteristat, phenol red and a "pH adjuster", i.e. a buffer) disclosed by Applicant are also well known in the art, as disclosed by both USPN 4,748,113 and USPN 5,314,804. The concept of separating the urea composition from the indicator composition is not novel, as evidenced by USPN 5,314,804. However, no prior art of record discloses the use of **powdered urea** in methods to detect the presence of urease in a gastrointestinal system, as claimed by Applicant in the present application. Therefore, the concept of keeping the urea composition in a dried, powdered form separate from the indicator composition, "in order to improve the shelf life

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of systems and devices designed to detect bacterial infections in the gastrointestinal tract" (page 6, lines 22-25 of the present Specification) is deemed novel compared to the prior art of record.

6. Independent Claims 1, 14 and 18 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

7. Dependent Claims 2-13, 14-17 and 19-22 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda T Guo whose telephone number is (703) 605-1200. The examiner can normally be reached on Mon - Fri (8:00am - 4:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on (703) 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lynda T Guo
Patent Examiner
December 12, 2002



RALPH GROMER
PRIMARY EXAMINER
GROUP 1200